

Activity Report

Quarter 1 2011/12 (April to June 2011)



NIHR CRN Activity Report 2011/12

Quarter 1

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1. INTRODUCTION

The NIHR Clinical Research Network

The National Institute for Health Research (NIHR) Clinical Research Network is an essential element in achieving the government's vision "to create a health research system in which the NHS supports outstanding individuals, working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public."

The role of the Clinical Research Network is to provide researchers with the practical support they need to make clinical studies happen in the NHS, so that more research takes place across England, and more patients can take part.

This practical support includes:

- Reducing the "red-tape" around setting up a study
- Funding the people and facilities needed to carry out research "on the ground", so research activity does not drain core NHS resources
- Helping researchers to identify suitable NHS sites, and recruit patients to take part in research studies
- Advising researchers on how to make their study "work" in the NHS environment

The Clinical Research Network comprises eight national Networks:

- Six "topic" Clinical Research Networks, which focus on specific disease areas: Cancer, Diabetes, Dementias and Neurodegenerative Diseases, Medicines for Children, Mental Health, and Stroke
- A Primary Care Research Network
- A "Comprehensive" Clinical Research Network, which supports all those health areas not covered by the topic Networks, and which provides full geographical coverage of England. The Comprehensive Clinical Research Network also provides NHS research management and governance activities for NIHR supported studies.

Information included in this report

This report provides key activity data from the Clinical Research Network. The data are presented in four parts:

- Clinical Research Network High Level Objectives
- Clinical Research Network Portfolio activity
- NHS Research Management and Governance activity
- Life-sciences Industry studies

It is **important to note** that data on studies and patient recruitment are uploaded to the Clinical Research Network Portfolio by the Chief Investigator (or their delegate) on an ongoing basis. Investigators are encouraged to upload data promptly, so that data reporting is accurate. However, to ensure maximum data capture, this data upload can occur up to six weeks after the end of each quarter, with an absolute cut-off imposed at 30 June each year. For this reason, data reports for the same quarter may change over the course of the reporting year.

Period covered by this report

This report reports activity in the period 01 April 2011 to 30 June 2011, which is Quarter 1 of the 2011/12 financial year.

Where figures are given for “year to date”, this refers to the Clinical Research Network financial year, which is 01 April 2011 to 31 March 2012.

The information contained in the report represents the most complete information available at the time of publication.

Dissemination

This report is produced by the Clinical Research Network Coordinating Centre, which is responsible for collating and publishing activity and performance data for the NIHR Clinical Research Network as a whole.

It is the policy of the Clinical Research Network Coordinating Centre to be open and transparent in its activities and its associated impact. All Quarterly and Annual Reports are therefore published on our website, and can be accessed using this link:
http://www.crncc.nihr.ac.uk/about_us/performance_objectives.htm

The data presented in this report may be quoted in presentations and papers. However, we would ask that the title and issue date of the report is used, to avoid any confusion about the period to which the figures relate and the time at which the data were reported.

Further information

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2. CLINICAL RESEARCH NETWORK HIGH LEVEL OBJECTIVES

2.1 Introduction

The Clinical Research Network High Level Objectives are our overarching objectives for the five-year period 2010 -15. However, High Level Objective 1 takes 1 April 2009 as the start point.

The objectives are focused on delivery outcomes. They act as a management mechanism for driving forward our performance, and provide defined and agreed criteria for gauging improvement over time.

Table 2.1 presents the following information:

- Objective: the organisational goal for the Clinical Research Network
- Measure: the number or quantity that will be used to measure progress against the objective
- Target: the value of the measure that is the target value
- Timescale: the date by which the target value will be achieved, and therefore the timescale for the Clinical Research Network to reach the target (from the start date of 1 April 2010)

The introduction of the High Level Objectives has necessitated some new information gathering requirements and also some changes to underlying information systems.

These changes are being rolled out in a phased way, with full reporting on all High Level Objectives commencing from April 2011.

Table 2.1: Clinical Research Network High Level Objectives 2010-2015

Objective		Measure	Target	Timescale
1	Double the number of participants recruited into NIHR CRN Portfolio studies	Number of participants recruited in a reporting quarter into NIHR CRN Portfolio studies	125,000	4 years (31 March 2014)
2	Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment target and time	2A: Proportion of commercial contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed Network sites	80%	2 years (31 March 2012)
		2B: Proportion of non-commercial studies managed by Registered CTUs achieving or surpassing their recruitment target during their planned recruitment period	80%	3 years (31 March 2013)
		2C: Proportion of non-commercial studies not managed by Registered CTUs achieving or surpassing their recruitment target during their planned recruitment period	80%	5 years (31 March 2015)
3	Increase the percentage of commercial contract studies delivered through the NIHR CRN	Number of commercial contract studies on the NIHR CRN Portfolio as a percentage of the total commercial MHRA CTA approvals for Phase II–IV studies, on an annual basis	60%	4 years (31 Dec 2013)
4	Reduce the time taken to achieve NHS permission through CSP for NIHR studies	Proportion of studies obtaining NHS permission within 40 calendar days (from receipt of a valid complete application)	80%	3 years (31 March 2013)
5	Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies	5A: Proportion of commercial contract studies achieving first participant recruited within 30 calendar days of NHS Permission being issued, at confirmed Network sites	80%	2 years (31 March 2012)
		5B: Proportion of non-commercial studies managed by Registered CTUs achieving first participant recruited within 30 calendar days of NHS Permission being issued	80%	3 years (31 March 2013)
		5C: Proportion of non-commercial studies not managed by Registered CTUs achieving first participant recruited within 30 calendar days of NHS Permission being issued	80%	5 years (31 March 2015)
6	Increase the percentage of NHS Trusts participating in NIHR CRN Portfolio studies	Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio studies	98%	3 years (31 March 2013)

2.2 Summary data on performance to date

Table 2.2: Clinical Research Network High Level Objectives – summary on performance to date

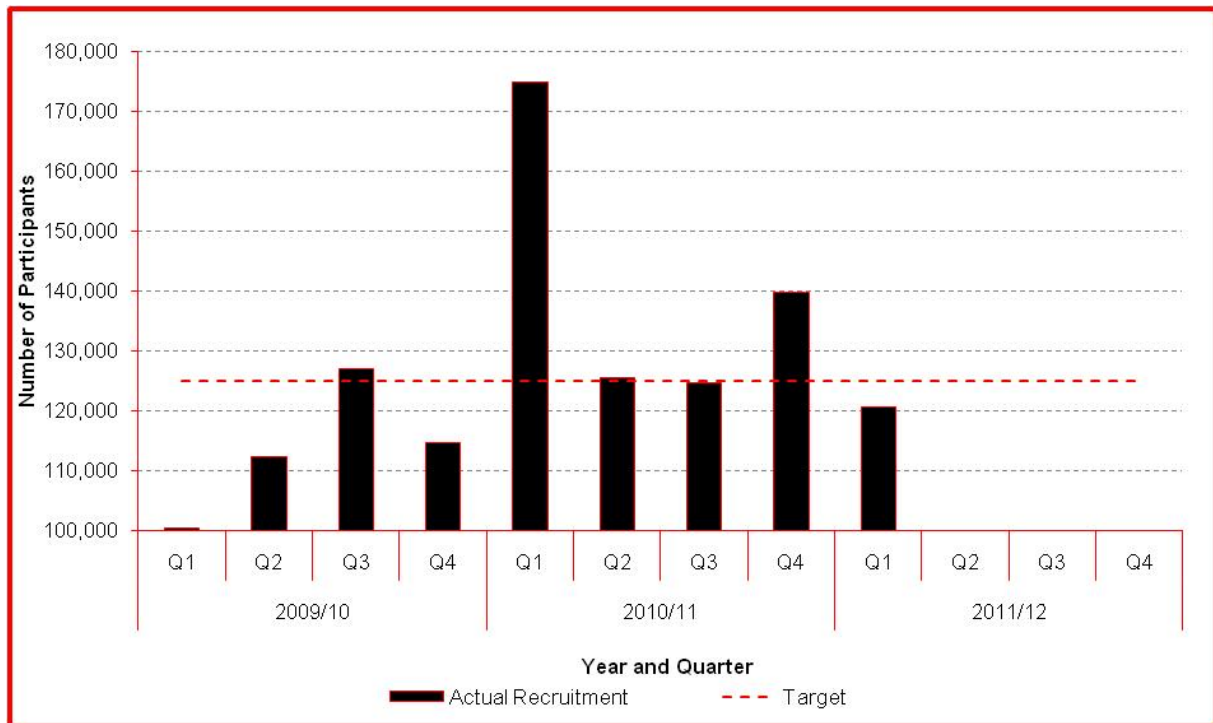
Objective	Target	2010/11	2011/12			
			Q1	Q2	Q3	Q4
1	125,000	141,175 ¹	120,585			
2A	80%	21%	17%			
2B	80%	100%	50%			
2C	80%	38%	44%			
3	60%	60%	63%			
4	80%	8%	11%			
5A	80%	52%	44%			
5B	80%	22%	17%			
5C	80%	38%	40%			
6	98%	97%	97%			

¹ Quarterly average

2.3 High Level Objective 1

Double the Number of Participants Recruited into NIHR Clinical Research Network Portfolio Studies

Fig 2.3: Total Number of Participants Recruited into NIHR Clinical Research Network Portfolio Studies



A total of 120,585 participants were recruited into CRN Portfolio studies in this quarter, against the quarterly target of 125,000.

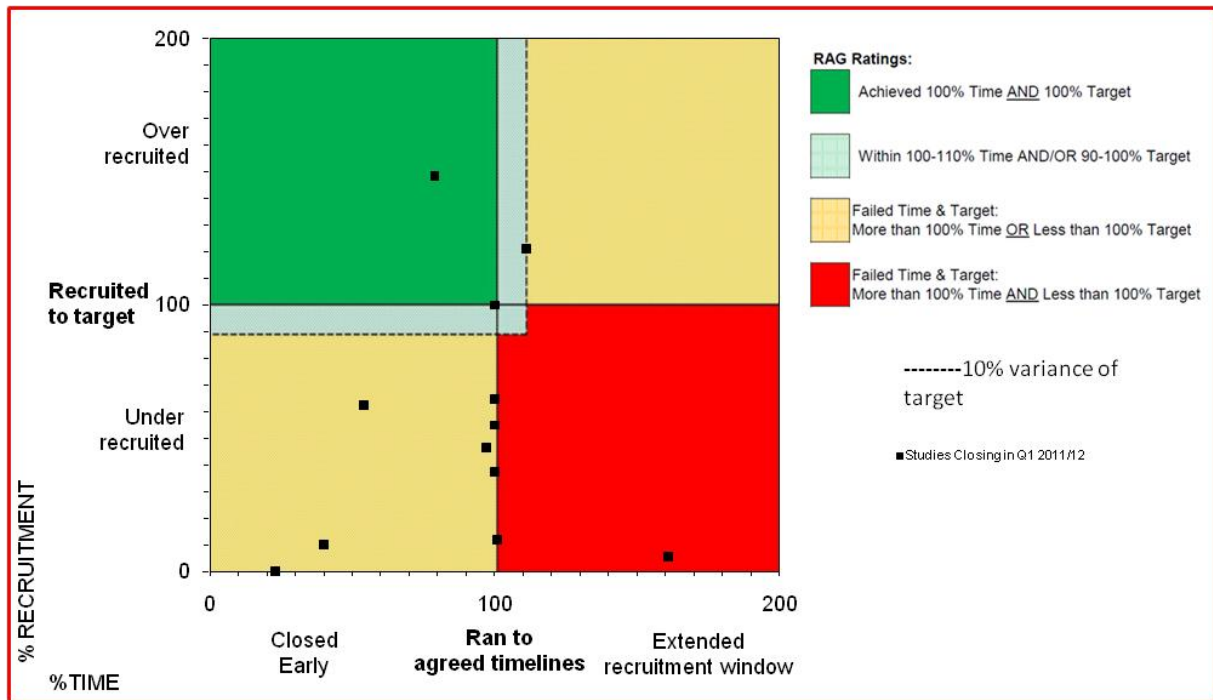
This is fewer participants than were recruited in each quarter of 2010/11; figure 2.3 however, illustrates an increase in recruitment in 2010/11 across all quarters when compared to the last Activity Report (Quarter 4, 2010/11, as a result of an increase in recruitment upload activity in preparation for the annual data cut which was taken at the end of June 2011. Bearing in mind the present CRN Portfolio recruitment reporting process (see Section 1) and experience of data upload behaviour in 2010/11, we are content that the current data represent satisfactory progress towards consistent attainment of the target recruitment level by 31 March 2014.

2.4 High Level Objective 2

Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment target and time

High Level Objective 2A: Proportion of commercial contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed Network sites

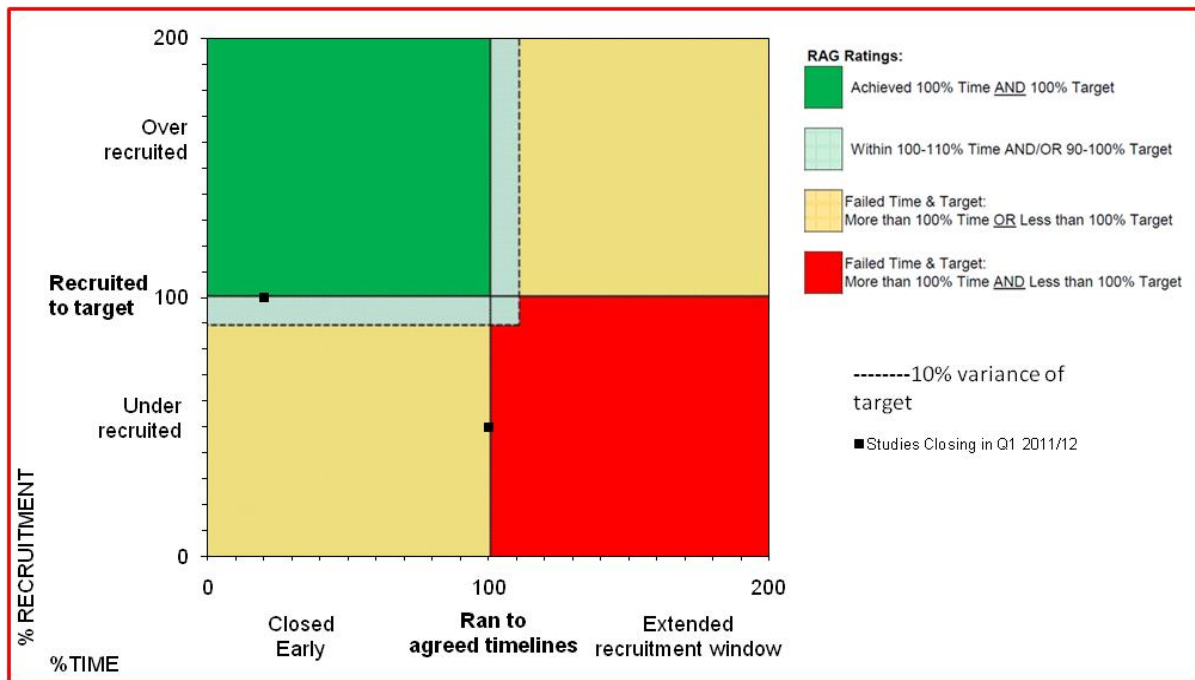
Fig 2.4: Commercial Contract Studies, Recruitment to Time and Target



The percentage of studies delivering within both 100% to time and target was 17%. This is disappointing and despite inter-quarter variation, the network expects to see an increase each quarter in this percentage. Of the 12 studies that closed in this quarter, only 2 achieved 100% of their recruitment target within 100% of the planned timeline. One study despite surpassing its recruitment target exceeded the original planned timeline by 10% and so is not included in the successful study delivery category. Of the studies that failed to deliver to time and target, one was prematurely terminated globally by the sponsor due to safety reasons. Unfortunately, a combination of global competitive recruitment and slow set up times still impacts on the ability of sites to recruit their target within the planned timelines. It is anticipated that the impact of CSP improvements will be realised as the financial year commences and study start up times should significantly decrease. This will allow sites adequate time to achieve their recruitment targets.

High Level Objective 2B: Proportion of non-commercial studies managed by Registered CTUs achieving or surpassing their recruitment target during their planned recruitment period

Fig 2.5: Non-Commercial Studies Managed by Registered CTUs, Recruitment to Time and Target



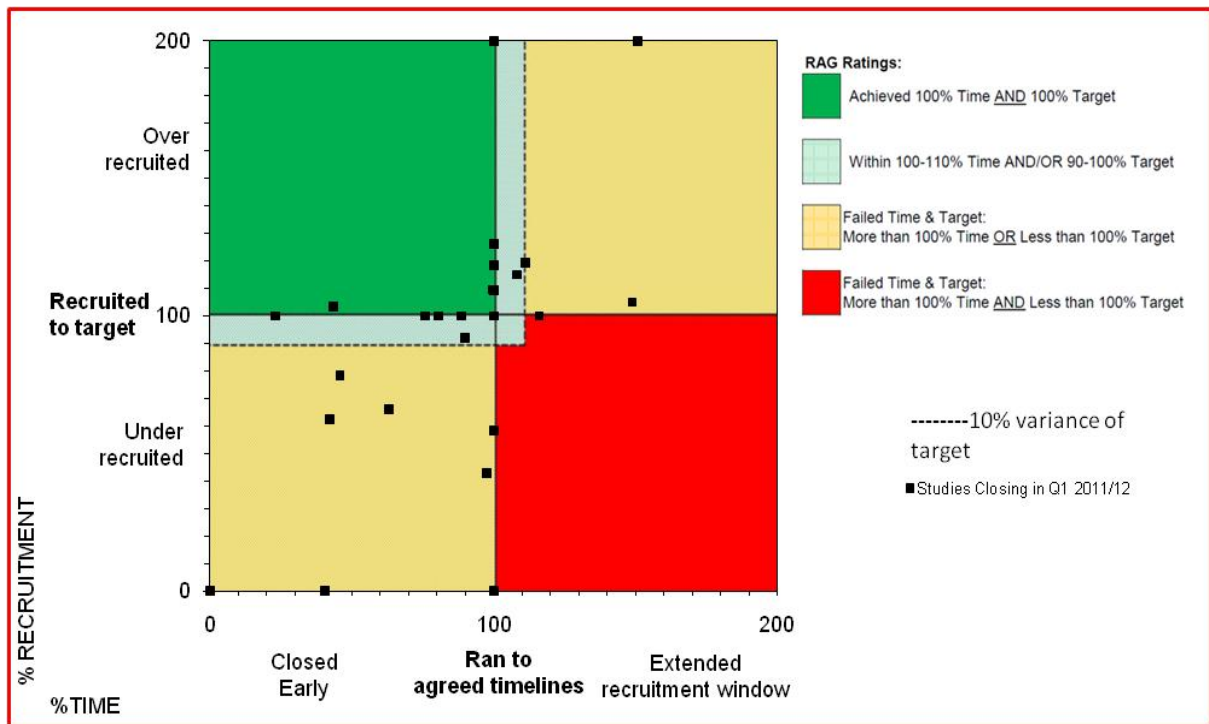
We are working towards a target of 80% of non-commercial studies managed by Registered Clinical Trials Units (CTUs) achieving or surpassing their recruitment target during their planned recruitment period, by March 2013.

In Quarter 1 of 2011/12 two studies fulfilled the criteria for inclusion in this objective. As figure 2.5 shows, one of these successfully recruited its target number of patients within its planned recruitment period. The other study closed on time, and although it did not recruit its planned number of participants, the study was considered to be a success for the network – as a feasibility study, it fulfilled its purpose, because it recruited the number of participants needed to inform the development of a protocol for a larger study.

It is too early to assess trends in our performance against this objective, but we expect to be able to do so in future quarters of 2011/12.

High Level Objective 2C: Proportion of non-commercial studies not managed by Registered CTUs achieving or surpassing their recruitment target during their planned recruitment period

Fig 2.6: Non-Commercial Studies Not Managed by Registered CTUs, Recruitment to Time and Target



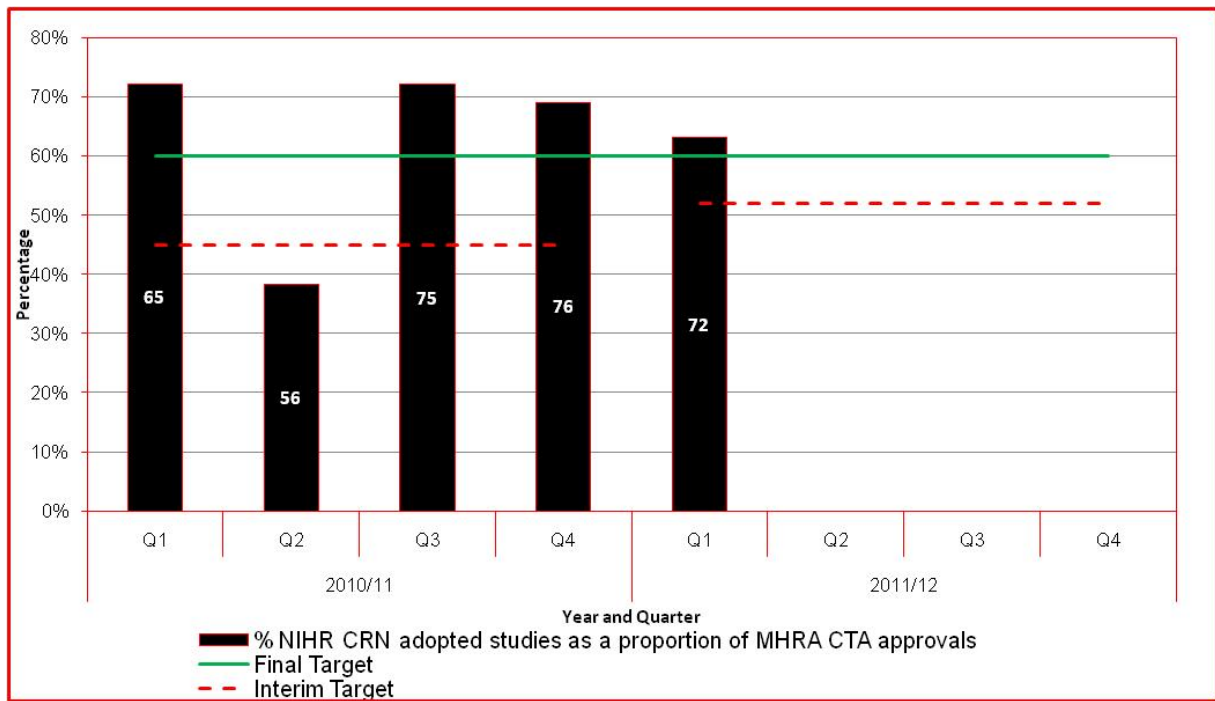
We are working towards a target of 80% of non-commercial studies NOT managed by Registered Clinical Trials Units (CTUs) meeting this objective by March 2015.

In Quarter 1 2011/12 44% of studies met this objective; this compares to 38% in the 2010/11 year. A further 16% of studies in Quarter 1 were “near misses” – those which exceeded the planned recruitment time by up to 10% or under-recruited by up to 10%. Whilst recognising that the number of studies measured is relatively small (25 studies in Quarter 1, as represented in figure 2.6), we are encouraged by the positive trend in performance on this objective.

2.5 High Level Objective 3

Increase the percentage of commercial contract studies delivered through the NIHR CRN

Fig 2.7: NIHR CRN Adopted Studies as a Proportion of MHRA CTA Approvals



In 2010/11 we met our HLO to increase the percentage of commercial contract studies delivered through the NIHR CRN and reached our target of 60%. This is demonstrated as the number of commercial contract studies on the NIHR CRN Portfolio as a percentage of the total commercial MHRA CTA approvals for Phase II–IV studies. It is encouraging to note that the percentage for Quarter 1 2011/12 is 63%, demonstrating the continued growth of the NIHR CRN portfolio of commercial contract research and the high level of positive engagement with the Life Sciences Industry. We are now working with 549 unique companies; a heterogeneous mix of Pharma, Biotech, Medtech and Contract Research Organisations. This data continues to suggest that the NIHR CRN is now embedded within the Industry's processes for setting up and delivering contract research within the NHS in England, although continued close collaboration is essential to build and maintain this relationship.

2.6 High Level Objective 4

Reduce the time taken to achieve NHS permission through CSP for NIHR studies

Fig 2.8: Proportion of Studies Obtaining NHS Permission within 40 Days

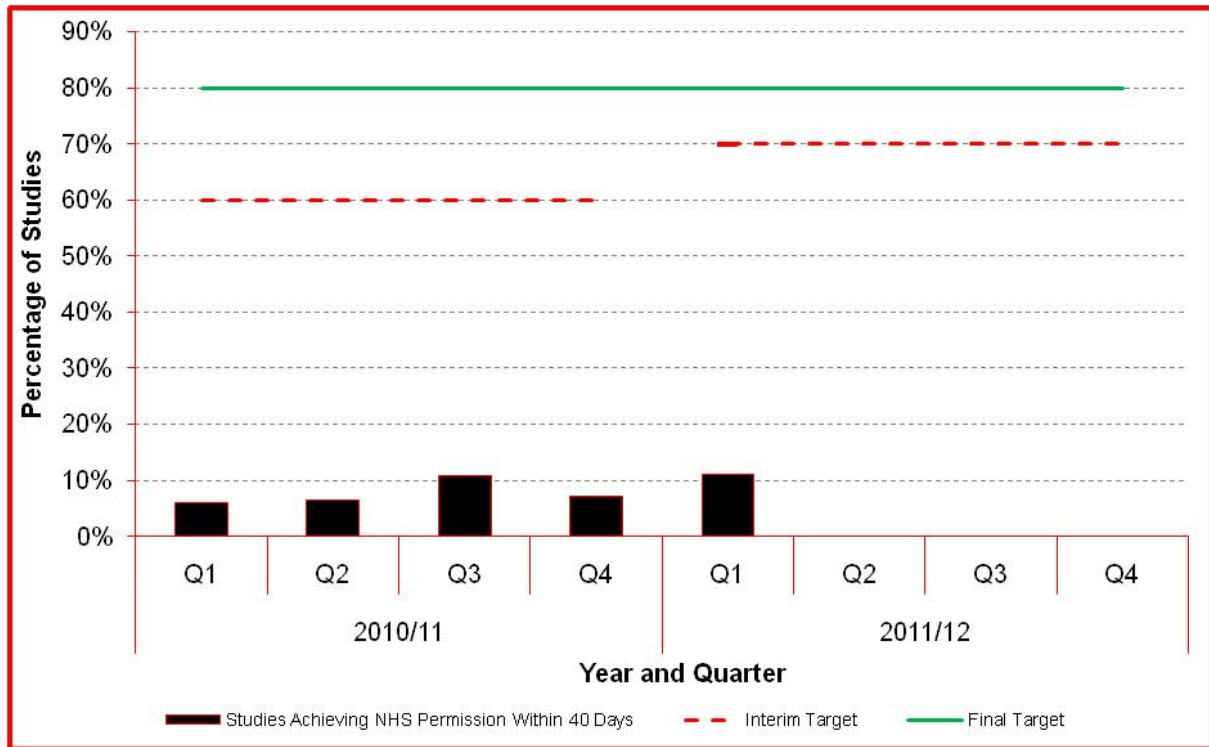


Figure 2.8 shows the percentage of studies achieving permission within 40 days within that quarter. Although there has been an improvement in the percentage of studies achieving the target in the last quarter, there is not yet a clear trend of improvement in the percentage of studies meeting target.

In recognition of the lack of improvement in NHS permission timelines since the launch of CSP, a major improvement programme was launched with the CLRN at the start of Quarter 3 2010/11. The programme covered changes to process, learning from existing good practice and from the North West Exemplar programme, and building on the principles identified through the development of the NIHR Research Support Services. A major work stream for the latter part of 2010/11 and for 2011/12 has been the development of the new NIHR R&D Management Information System CSP Module for launch in summer 2011.

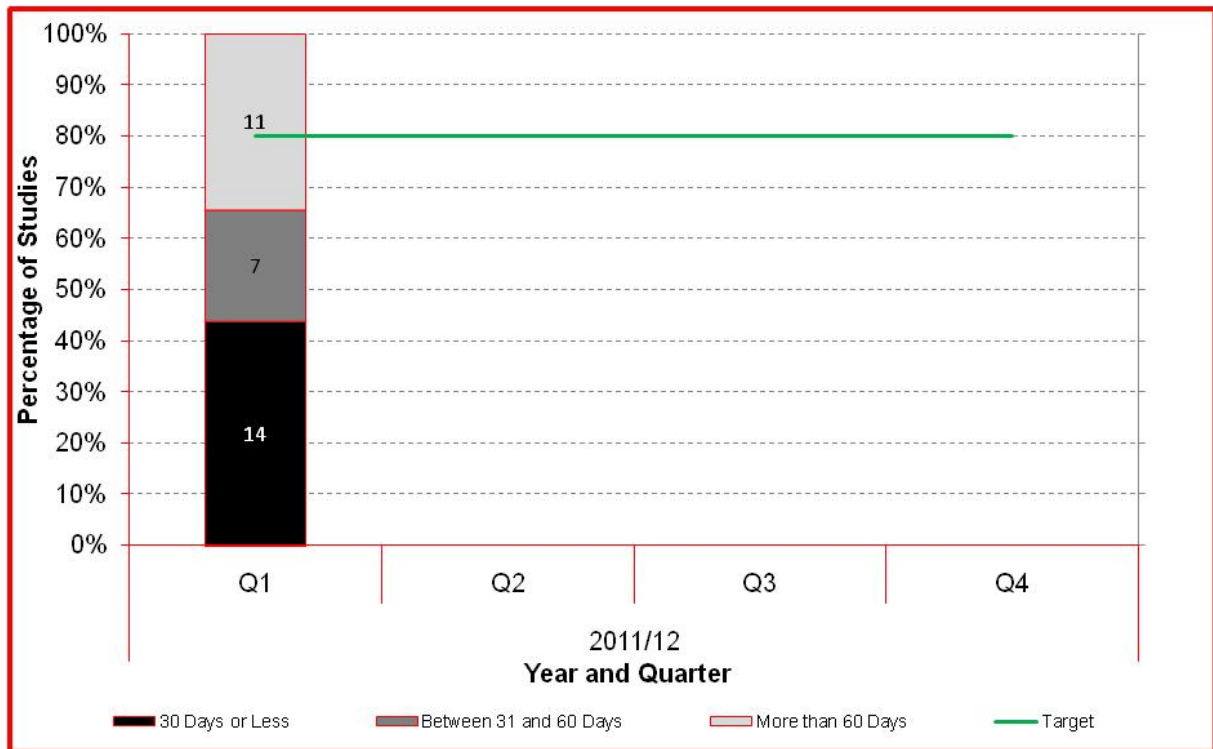
This measure reflects all the sites included in the application for a study, and sites are often set up over a considerable time period. There is therefore an expected lag time of many months from the start of study set-up at the first site to completion of study set-up at the last site, and inclusion in these metrics. Although more detailed reporting shown in Section 4 of this Report reveals some improvement in median NHS permission times in Quarter 1 2011/12, this would not be expected to be reflected yet in any significant improvement in the overall measure during the time period shown.

2.7 High Level Objective 5

Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies

High Level Objective 5A: Proportion of commercial contract studies achieving first participant recruited within 30 calendar days of NHS Permission being issued, at confirmed Network sites

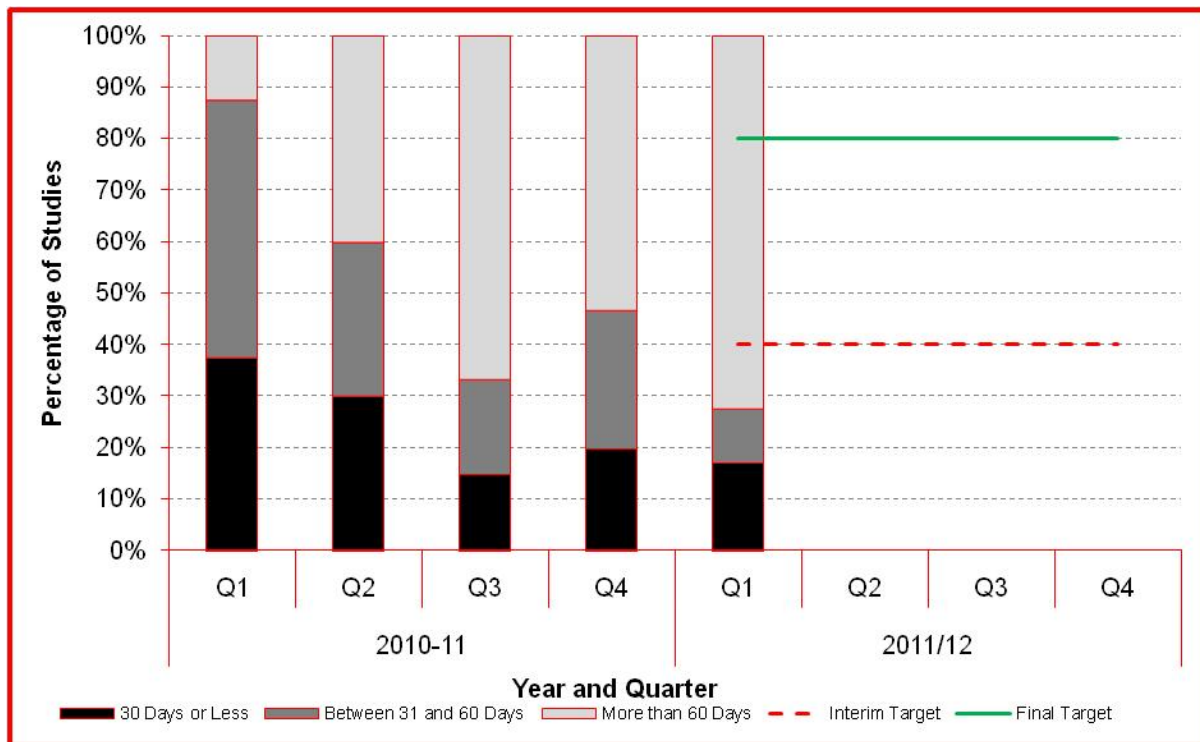
Fig 2.9: Proportion of Commercial Contract Studies, by the Number of Calendar Days from NHS Permission Issued to First Participant Recruited



44 % of the 32 commercial studies included in the Quarter 1 analysis recruited their first participant within 30 days of being granted NHS permission. This is slightly lower than the previous annual average of 52% but inter quarter variation is not unexpected. This objective does not exclude studies which have a recruitment rate of less than one patient per month and where patients are from a rare disease population. Initiatives to embed a more proactive approach to site set up and the need for patient pre-screening activities are underway with both industry and investigators. These should improve the ability of sites to pre-identify patients in advance of the study opening for recruitment and ensure there are no delays to enrolling the first patient after NHS permission has been granted.

High Level Objective 5B: Proportion of non-commercial studies managed by Registered CTUs achieving first participant recruited within 30 calendar days of NHS Permission being issued

Fig 2.10: Proportion of Non-Commercial Studies by Registered CTUs, by the Number of Calendar Days from NHS Permission Issued to First Participant Recruited



We are working towards a target of 80% of non-commercial studies managed by Registered Clinical Trials Units achieving this objective by March 2013. Performance in Quarter 1 2011/12 fell considerably short of this ultimate target, with 17% of relevant studies recruiting their first participant within 30 calendar days of NHS Permission being issued. This compares to 22% in the year 2010/11. As shown in figure 2.10, Quarter 1 also saw an increase in the percentage of studies which took longer than 60 days to recruit their first patient, compared with the four previous quarters.

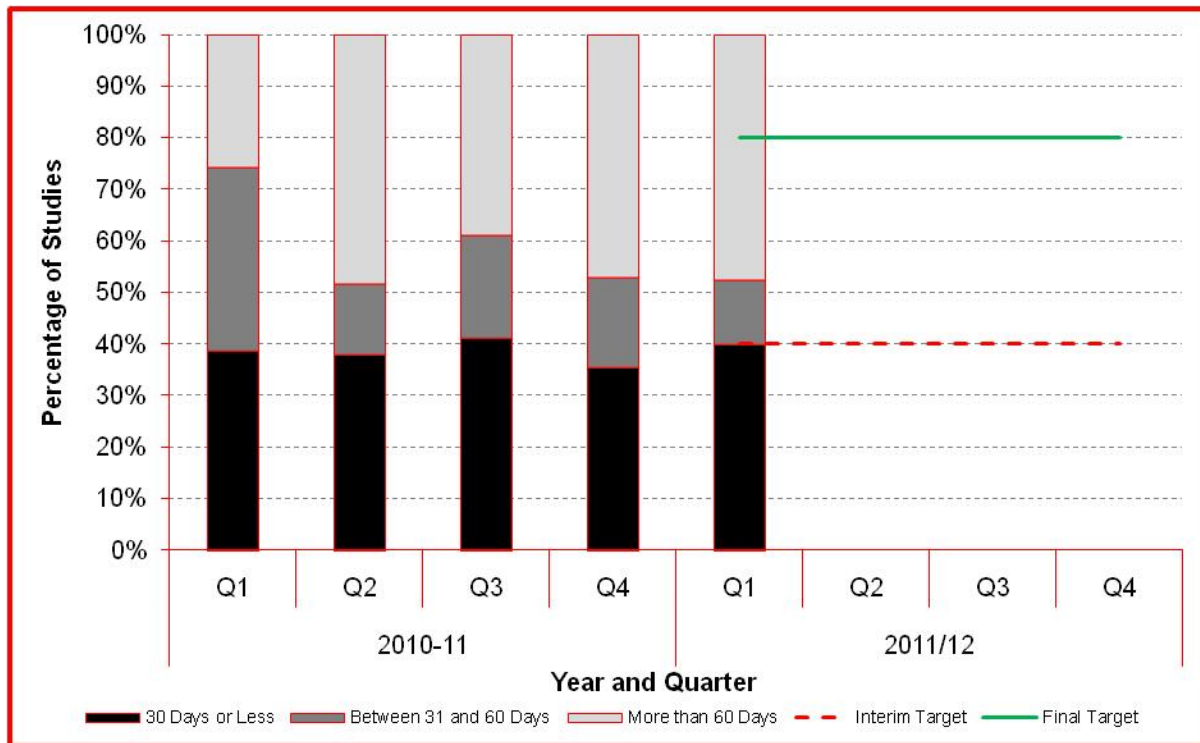
Performance is disappointing when compared to High Level Objective 5C, which indicates that studies NOT managed by Registered Clinical Trials Units are achieving better performance against this measure. It is possible that CTU-managed studies as a group are of a higher degree of complexity than non CTU-managed studies, and so recruitment to plan may be less likely. It is also worth noting that some studies may still not be open to recruitment once NHS Permission is granted, as there may be other study procedures to put in place such as study medication being available at site before the study is ready to recruit.

It is also important to note that the data points and calculations used to measure the Clinical Research Network's performance against this and other measures have only recently been defined, and it is likely that once the networks become familiar with them, data quality and completeness will increase, which is likely to result in an improvement in the figures during 2011/12.

Work continues to identify and address the issues that are preventing studies from recruiting their first participant within 30 days of NHS Permission being issued.

High Level Objective 5C: Proportion of non-commercial studies not managed by Registered CTUs achieving first participant recruited within 30 calendar days of NHS Permission being issued

Fig 2.11: Proportion of Non-Commercial Studies Non Managed by Registered CTUs, by the Number of Calendar Days from NHS Permission Issued to First Participant Recruited



We are working towards a target of 80% of non-commercial studies NOT managed by Registered CTUs achieving this objective by March 2015, with an interim target of 40% for the year 2011/12.

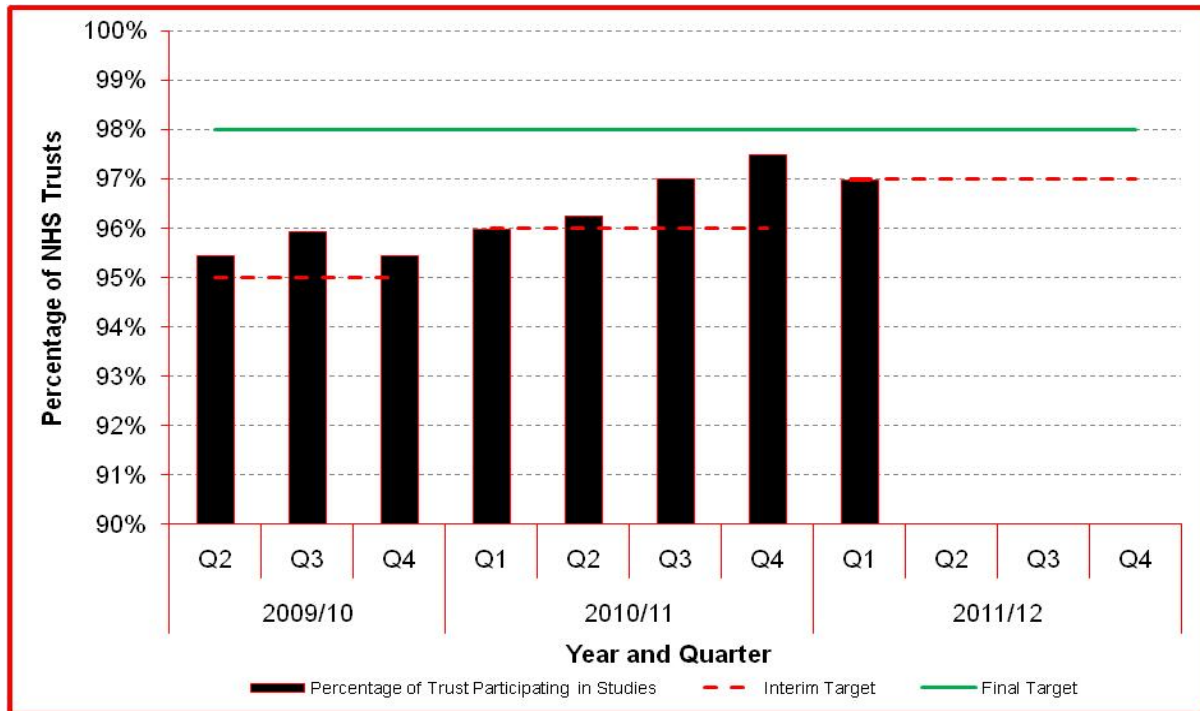
As figure 2.11 shows, the Clinical Research Network met its 2011/12 target of 40% in Quarter 1 2011/12, which is encouraging. It represents a slight improvement in performance from 2010/11, in which 38% of relevant studies recruited their first participant within 30 calendar days of NHS Permission being issued.

The trend over the last five quarters is relatively flat. Work continues to understand and address the issues that are preventing studies from recruiting their first participant within 30 days of NHS Permission being issued, and we expect that performance will improve during 2011/12.

2.4 High Level Objective 6

Increase the percentage of NHS Trusts participating in NIHR Clinical Research Network Portfolio studies

Fig 2.12: Percentage of Trusts Participating in NIHR Clinical Research Network Portfolio Studies



The proportion of NHS Trusts actively recruiting to NIHR CRN Portfolio studies slipped by 0.5% this quarter, from 97.5% to 97%. In this quarter, 379 of the 397 local NHS Trusts in England were actively recruiting. Table 2.14 lists those NHS organisations that have not recruited in one or more of the past four quarters. It reflects the fact non-active Trusts are primarily ambulance Trusts and community / social care Trusts. It should be noted that there the portfolio of pre-hospital studies is very small, and so ambulance Trusts simply do not have appropriate studies to which their services can recruit. Regarding community care Trusts, many are new organisations created as a result of Transforming Community Services. Through the NIHR Comprehensive Local Research Networks in particular, the CRN shall continue to develop strategies to develop research participation in community trusts and in the very small number of other non-active NHS Trusts. We are confident that the 98% goal will be attained by the target date of 31 March 2013.

Table 2.13 Number and percentage of active NHS organisations this quarter, for each NHS organisation type

Organisation type	Number of Organisations	Number of Active Organisations	Percentage of Active Organisations
Acute	169	167	98.82%
Mental Health/Social/Community	72	66	91.67%
Primary Care Trust	145	140	96.55%
Ambulance	11	6	54.55%

Table 2.14 List of NHS organisations that have not reported recruitment activity in one or more of the past four quarters

Organisation Name	Organisation Type	Activity in past four quarters			
		2010/11 Q2	2010/11 Q3	2010/11 Q4	2011/12 Q1
BEXLEY CARE TRUST	Mental Health/Social/Community	✓	✗	✓	✗
BOLTON NHS FOUNDATION TRUST	Acute	✗	✗	✗	✓
BRIDGEWATER COMMUNITY HEALTHCARE NHS TRUST	Mental Health/Social/Community	✗	✗	✗	✗
BRIGHTON AND HOVE CITY PCT	Primary Care Trust	✓	✓	✓	✗
CALDERSTONES PARTNERSHIP NHS FOUNDATION TRUST	Mental Health/Social/Community	✗	✓	✗	✓
CAMBRIDGESHIRE COMMUNITY SERVICES NHS TRUST	Acute	✗	✗	✓	✓
CENTRAL LONDON COMMUNITY HEALTHCARE NHS TRUST	Mental Health/Social/Community	✗	✗	✗	✗
CITY AND HACKNEY TEACHING PCT	Primary Care Trust	✓	✓	✓	✗

EAST MIDLANDS AMBULANCE SERVICE NHS TRUST	Ambulance	x	x	✓	✓
EAST OF ENGLAND AMBULANCE SERVICE NHS TRUST	Ambulance	✓	✓	x	✓
EAST SUSSEX DOWNS AND WEALD PCT	Primary Care Trust	✓	✓	✓	x
GREAT WESTERN AMBULANCE SERVICE NHS TRUST	Ambulance	x	✓	x	x
HERTFORDSHIRE COMMUNITY NHS TRUST	Mental Health/ Social/Community	x	x	x	x
HEYWOOD, MIDDLETON AND ROCHDALE PCT	Primary Care Trust	x	x	✓	✓
HILLINGDON PCT	Primary Care Trust	✓	✓	✓	x
KINGSTON PCT	Primary Care Trust	✓	✓	✓	x
LEEDS COMMUNITY HEALTHCARE NHS TRUST	Acute	x	x	x	x
LIVERPOOL COMMUNITY HEALTH NHS TRUST	Mental Health/ Social/Community	x	x	x	x
NORFOLK COMMUNITY HEALTH AND CARE NHS TRUST	Mental Health/ Social/Community	x	✓	✓	✓
NORTH WEST AMBULANCE SERVICE NHS TRUST	Ambulance	x	x	x	x
OXFORDSHIRE LEARNING DISABILITY NHS TRUST	Mental Health/ Social/Community	x	x	x	✓
ROYAL NATIONAL ORTHOPAEDIC HOSPITAL NHS TRUST	Acute	x	x	x	✓

SOUTH CENTRAL AMBULANCE SERVICE NHS TRUST	Ambulance	x	✓	✓	x
SOUTH EAST COAST AMBULANCE SERVICE NHS FOUNDATION TRUST	Ambulance	x	x	x	x
SOUTH WESTERN AMBULANCE SERVICE NHS FOUNDATION TRUST	Ambulance	x	x	x	✓
TAVISTOCK AND PORTMAN NHS FOUNDATION TRUST	Mental Health/ Social/Community	x	✓	✓	✓
THE ROBERT JONES AND AGNES HUNT ORTHOPAEDIC HOSPITAL NHS FOUNDATION TRUST	Acute	x	x	x	✓
UNIVERSITY HOSPITALS OF MORECAMBE BAY NHS FOUNDATION TRUST	Acute	✓	x	x	✓
WALSALL HEALTHCARE NHS TRUST	Mental Health/ Social/Community	x	x	✓	x
WARRINGTON AND HALTON HOSPITALS NHS FOUNDATION TRUST	Acute	x	✓	✓	✓
WIRRAL COMMUNITY NHS TRUST	Acute	x	x	x	x
YORKSHIRE AMBULANCE SERVICE NHS TRUST	Ambulance	x	x	✓	x

Table 2.15: Recruitment per million resident population in each NHS Strategic Health Authority area ²

SHA	Total Recruitment Q1 2011/12	Population (million)	Total Recruitment Q1 2011/12 per million population
South Central SHA	16,280	3.929	4,144
West Midlands SHA	15,587	5.332	2,923
South West SHA	13,988	5.045	2,773
London SHA	18,636	7.43	2,508
North East SHA	6,314	2.545	2,481
North West SHA	16,667	6.861	2,429
Yorkshire and Humber SHA	10,640	5.037	2,112
East Midlands SHA	8,798	4.248	2,071
East of England SHA	10,775	5.49	1,963
South East Coast SHA	2,900	4.175	695
TOTAL	120,585	50.092	2,407

² SHA resident population based on Office of National Statistics mid-2004 Resident Population Estimates.

3. CLINICAL RESEARCH NETWORK PORTFOLIO ACTIVITY

The NIHR Clinical Research Network Portfolio (CRN Portfolio) is a collection of high quality clinical research studies that are eligible for consideration for Clinical Research Network support. Some studies may receive support from more than one of the eight Clinical Research Networks. Where this is the case a "Lead Network" is allocated and for the purposes of this report, the number of studies and recruitment data are shown only against that Network.

The number of studies eligible for consideration for NIHR Clinical Research Network support and so entered onto the Portfolio Database, in each quarter is illustrated in figure 3.1. Non-commercial studies, including those that are automatically eligible and those that are required to go through the non-commercial adoption process make up the greatest proportion of studies on the CRN Portfolio. This is a trend observed across all quarters since 2008/9 which is maintained in Quarter 1 of 2011/12.

Quarter 1 of 2011/12 has seen a decrease in the number of studies eligible for the CRN Portfolio in all study categories (i.e. commercial and non-commercial studies) compared to all four quarters of 2010/11. Moreover, Quarter 1 2011/12 has the fewest number of studies eligible for the CRN Portfolio per quarter across all quarters and years. A Quarter 1 decrease on the previous year's Quarter 4 was also observed between 2008/9 and 2009/10 but not between subsequent years (2009/10 and 2010/11).

The number of new studies entered onto the Portfolio Database is limited by issues such as the levels of funding available to commission research and the number of high quality research proposals developed and submitted for funding. The decrease in the number of studies eligible for consideration for CRN support and hence included in the CRN Portfolio this quarter, may therefore be a result of a reduction in the amount of research grant funding available from the Government and charity sector and hence a reduction in the overall number of clinical research studies being funded. Similarly a reduction in the number of clinical research studies being funded could also be as a result of Government and charity funders supporting larger, more complex studies.

Fig 3.1: Number of Studies Entered onto the Portfolio by Eligibility Type

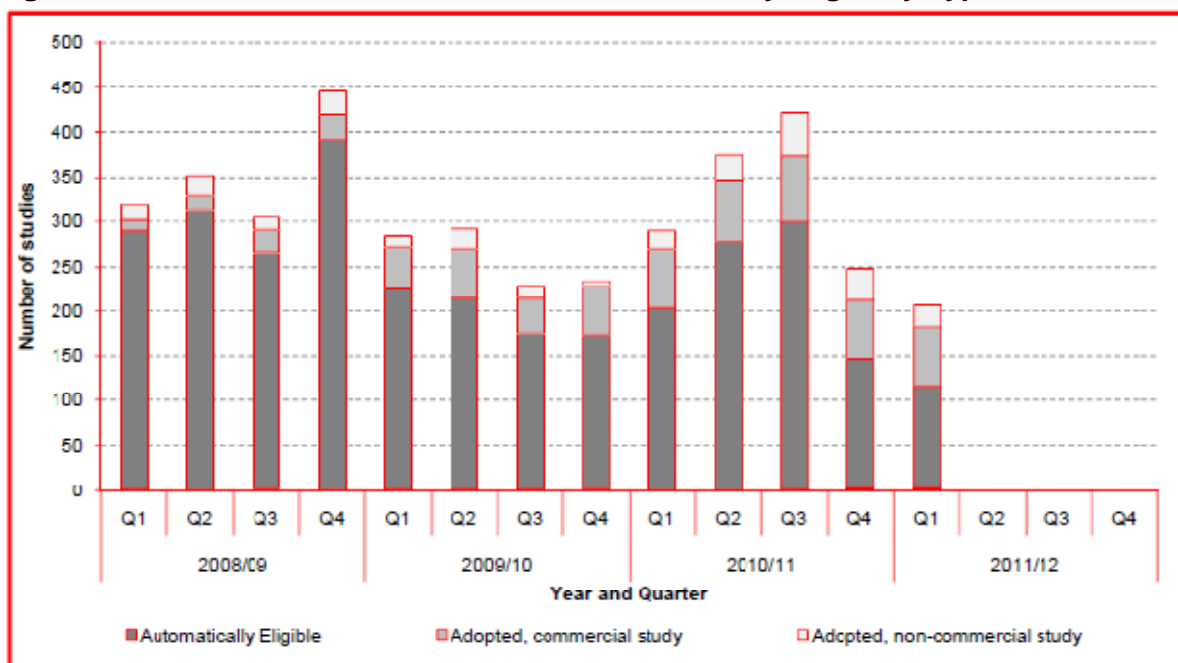
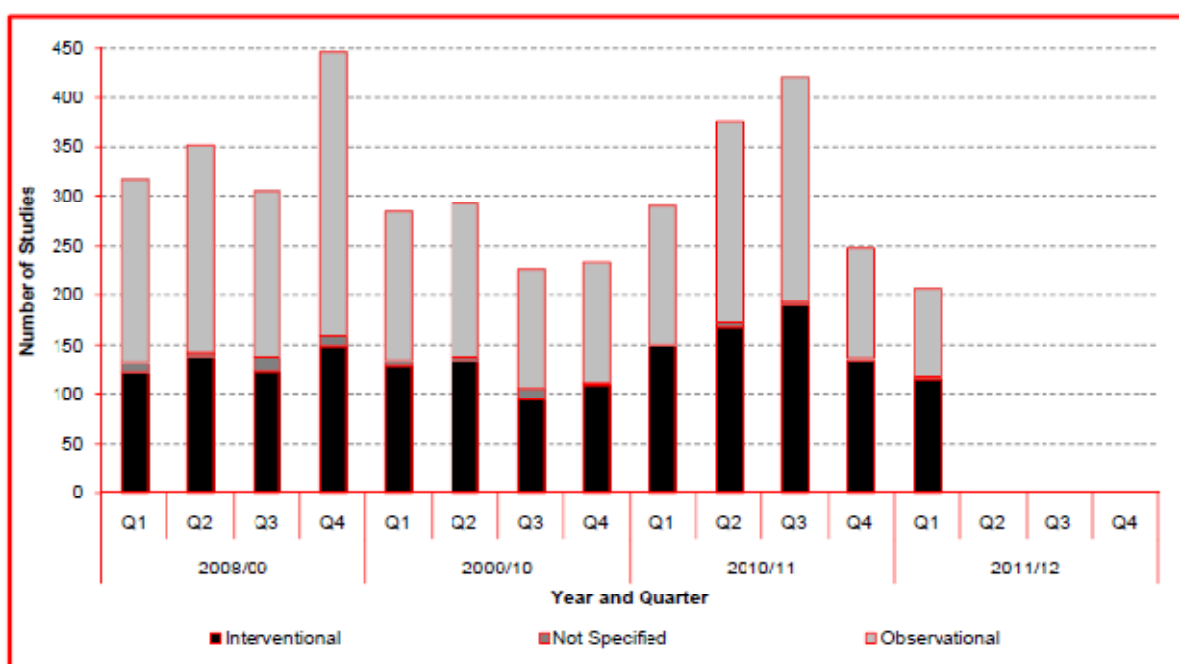


Figure 3.1 also gives an indication of the demand for support from the NIHR Clinical Research Network. It is expected that the Clinical Research Network should have the capacity to meet this demand with a reasonable balance of ongoing studies closing and new studies opening. Quarter 1 of 2011/12 has seen a decrease in the number of studies eligible for consideration for CRN support in comparison to both the previous quarter (Quarter 4 2010/11) and Quarter 1 2010/11. Despite this reduction in the number of new studies being considered eligible for CRN support in this quarter, the Clinical Research Network was still supporting some 2,761 open studies in Quarter 1 2011/12 (see table 3.3).

Fig 3.2: Number of Studies Entered onto the Portfolio by Primary Study Design



The NIHR Clinical Research Network supports a broad range of studies. Figure 3.2 provides the total number of interventional and observational studies deemed eligible for consideration for Clinical Research Network support in each quarter. As figure 3.2 illustrates, there is a good split in each quarter between observational and interventional studies and this trend is maintained in Quarter 1 of 2011/12 demonstrating that that NIHR Clinical Research Network continues to support a balanced portfolio of clinical research studies. Interestingly in Quarter 1 of 2011/12 as with Quarter 4 of 2010/11, the number of interventional studies (N=115 in Quarter 1 2011/12) deemed eligible for inclusion in the CRN Portfolio has surpassed the number of observational studies (N=87 in Quarter 1 2011/12). This observation gives credence to the hypothesis that research funding organisations may be moving towards funding fewer but more complex studies.

Table 3.3: Number of Studies Open to Recruitment, Reporting Recruitment and Recruitment by Network

Network	Number of Studies Open to Recruitment during Q1 2011/12	Total Number of Studies Reporting Recruitment in Q1 2011/12	Total Recruitment Q1 2011/12
Cancer	443	381	17,229
Comprehensive	1,476	1,153	60,283
Dementias & Neurodegenerative Disease	107	89	2,962
Diabetes	175	116	5,299
Medicines for Children	99	90	2,205
Mental Health	222	185	8,308
Primary Care	151	127	21,855
Stroke	88	76	2,444
TOTAL	2,761	2,217	120,585

The number of studies open to recruitment (table 3.3) gives a broad indication of the scale of opportunities for participants to take part in clinical research in the NHS in England. In addition it indicates the current level of recruitment related work being carried out by the Clinical Research Network. In this quarter, the number of studies open to recruitment has increased by 82 studies on Quarter 4 (2010/11) in which 2,679 studies were open to recruitment. The number of studies attributed to each of the Networks is also provided in table 3.3, illustrating a wide range in the number of studies being "lead" by each Network.

The number of studies reporting recruitment data in Quarter 1 2011/12 has decreased when compared to Quarter 4 2010/11 (N=2,264 studies) with 47 fewer open studies reporting recruitment data in Quarter 1 2011/12 than Quarter 4 2010/11. In this quarter (Quarter 1 2011/12) 80% of all open studies were reporting recruitment data (see figure 3.4). This demonstrates a downward trend in the number of studies reporting recruitment data since Quarter 1 of 2010/11. It is important to note that the number of studies reporting recruitment data may be an under representation of the number of studies that have recruited participants as some studies may not yet have uploaded their recruitment data into the national Portfolio Database. Study teams are asked to report recruitment data on a monthly basis although for some studies this is not as practical as for others which results in delays in the inclusion of some recruitment data in reports.

Fig 3.4 Percentage of Open Studies Reporting Recruitment

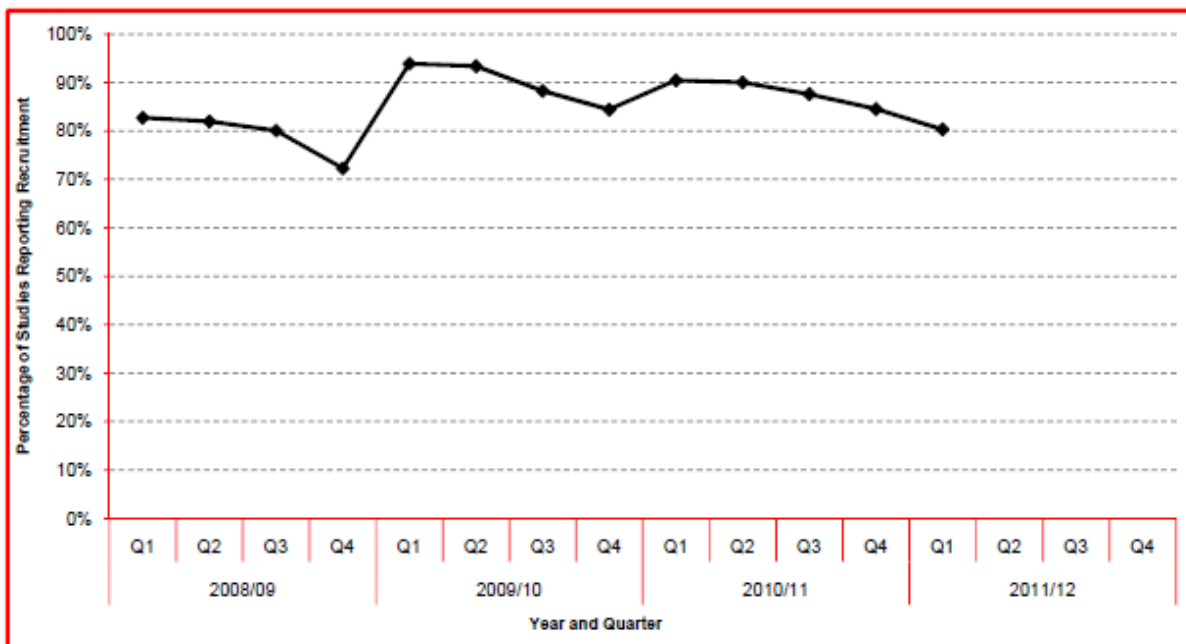


Table 3.5: Recruitment by Network

	2008/09				2009/10				2010/11				2011/12			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Cancer	19,932	19,995	18,336	12,690	10,996	12,866	15,015	15,281	18,526	17,393	15,679	19,594	17,229			
Comprehensive	47,572	27,787	30,568	20,997	49,460	52,355	55,854	53,812	116,173	69,918	63,509	72,258	60,283			
Dementias & Neurodegenerative Diseases	1,789	1,366	1,473	1,534	1,619	2,134	2,024	2,273	2,443	2,474	3,859	4,580	2,962			
Diabetes	4,620	9,106	7,260	5,023	6,703	13,333	10,492	6,492	9,219	8,461	6,101	10,804	5,299			
Medicines for Children	849	768	1,005	1,141	1,259	1,444	2,768	1,738	1,746	1,695	1,793	1,695	2,205			
Mental Health	4,745	3,203	3,672	2,926	11,233	12,396	15,506	12,546	14,857	10,559	10,649	7,048	8,308			
Primary Care	19,899	23,637	16,174	16,164	17,168	15,797	23,629	20,310	9,600	12,427	20,395	20,726	21,855			
Stroke	1,659	1,686	1,519	2,131	1,960	1,908	1,661	2,106	2,256	2,483	2,683	3,095	2,444			
Total	101,065	87,548	80,007	62,606	100,398	112,233	126,949	114,558	174,820	125,410	124,668	139,800	120,585			

In terms of total recruitment, 120,585 participants were recruited into CRN Portfolio studies in this quarter (tables 3.3 and 3.5). This is a decrease of 19,215 participants compared to the previous quarter (Q4, 2010/11) and a decrease of 54,235 participants when compared to Quarter 1 2010/11.

As with all quarters in previous years, the Comprehensive Clinical Research Network, which supports the greatest number of studies (table 3.3) also contributes the greatest number of recruits to the overall Quarter 1 2011/12 total. Five of the eight NIHR Clinical Research Networks reported a decrease in their recruitment in Quarter 1 2011/12 when compared with Q4 2010/11. Not all networks however have experienced this decrease with the Medicines for Children, Mental Health and the Primary Care Research Networks all reporting increases in recruitment in Q1 2011/12 when compared to the previous quarter (2010/11).

This may be a result of one or more of a number of external limiting factors, including:

- The type of study - observational studies tend to recruit a larger number of participants (figure 3.6) and are often less complex to deliver, whilst interventional studies where a new treatment or device is being investigated are more complex and may result in fewer participants (figure 3.6) for the same time and effort invested.
- The nature of the disease area - studies investigating rare conditions or hard to reach populations will by their nature recruit fewer participants.
- Closure of one or more high recruiting studies in the previous quarter where networks have experienced a decrease in recruitment this quarter. Or, alternatively for those networks observing an increase this quarter, the opening of one or more high recruiting studies (table 3.5).

Fig 3.6: Recruitment by Primary Study Design

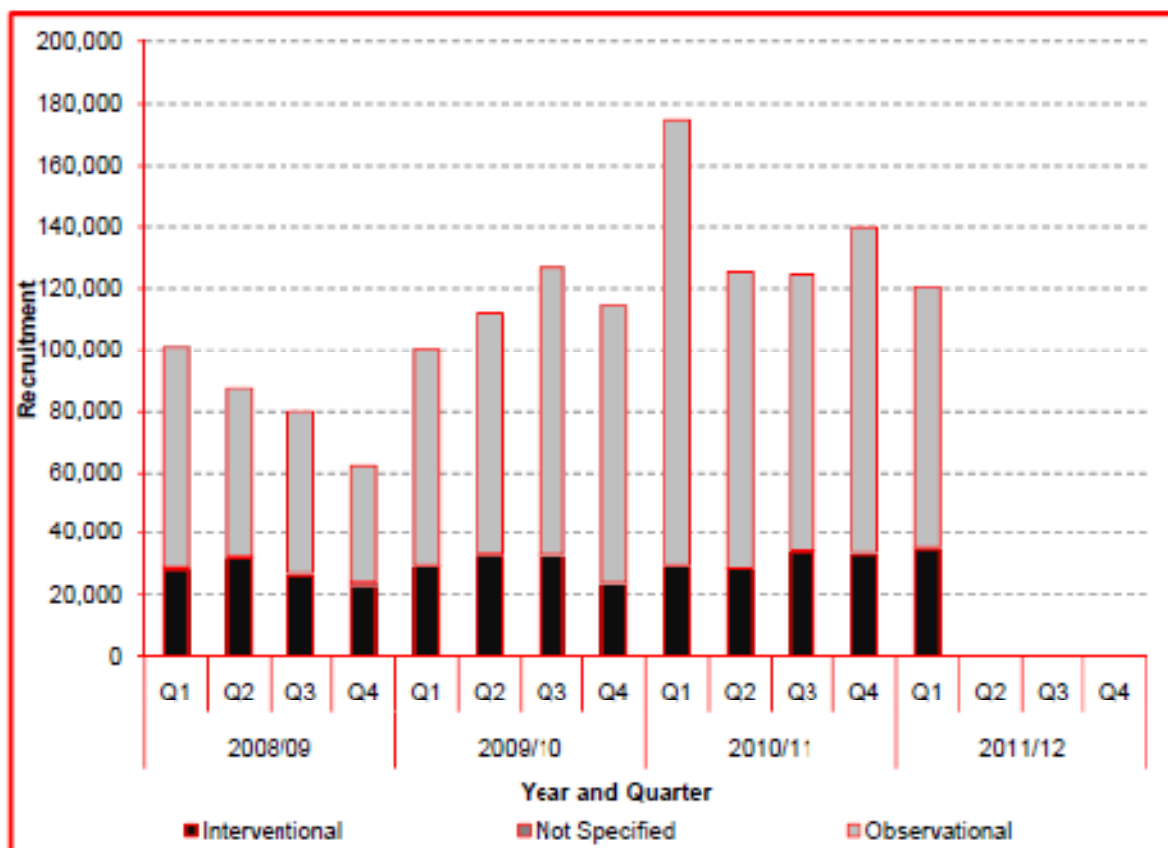


Figure 3.6 provides a breakdown of the total recruitment according to the primary study design. This illustrates that observational studies account for a greater proportion of total recruitment in comparison to interventional studies. This trend is maintained in this quarter despite a greater proportion of interventional studies than observational studies being added to the Portfolio Database. Interestingly recruitment into interventional studies is more consistent over time than that in observational studies (figure 3.6), this is likely to be accounted for by recruitment into a small number of very large observational studies in specific quarters.

In Quarter 1 2011/12 there were 85,455 recruits into observational studies compared to 106,289 recruits into observational studies in Quarter 4 2010/11 and 34,649 recruits into interventional studies in Quarter 1 2011/12 compared to 33,026 recruits in Quarter 4 2010/11. The overall decrease in recruitment seen this quarter is therefore primarily a result of decreased recruitment into observational studies. Interestingly the number of recruits to interventional studies increased in Quarter 1 2011/12 when compared to Quarter 4 2010/11, perhaps reflecting the increase in interventional studies added to the Portfolio Database in this and the previous quarter.

Fig 3.7 Recruitment by Network and Study Design

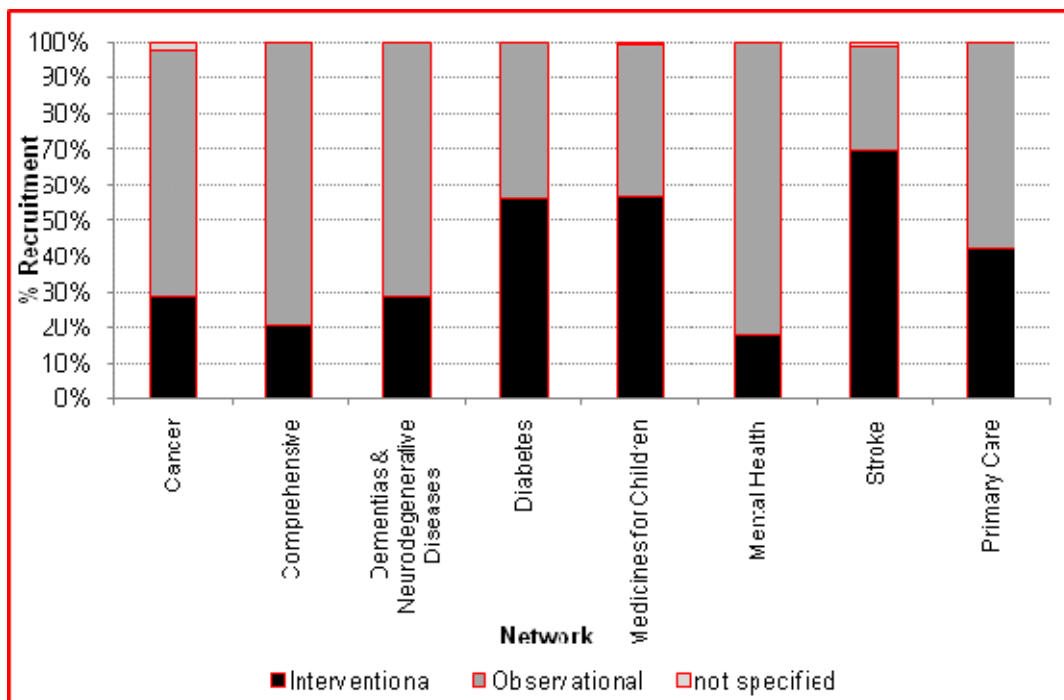


Figure 3.7 illustrates the breakdown of recruitment in each network by primary study design. Whilst overall recruitment into observational studies surpassed that into interventional studies in Quarter 1 2011/12 (figure 3.6), three networks (Diabetes, Medicines for Children and Stroke) didn't follow this trend and recruited more participants to interventional studies than observational studies. Moreover the Stroke Research Network recruited more than twice as many participants into interventional studies (N=1,699 participants) compared to observational studies (N=719 participants). This is likely to be a reflection of the number of interventional and observational studies within their portfolios

Table 3.8 Summary trend data

The Total Number of Studies Entered onto the Portfolio, over Time

	2008/09				2009/10				2010/11				2011/12
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
TOTAL NUMBER OF STUDIES	318	352	305	446	284	292	227	234	290	375	421	248	206

The Total Number of Studies Open to Recruitment, over Time

	2008/09				2009/10				2010/11				2011/12
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
TOTAL NUMBER OF STUDIES	1,677	1,765	1,836	1,887	2,091	2,183	2,268	2,305	2,417	2,476	2,577	2,679	2,761

The Total Number of Studies Reporting Recruitment, over Time

	2008/09				2009/10				2010/11				2011/12
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
TOTAL NUMBER OF STUDIES	1,387	1,446	1,470	1,364	1,963	2,038	2,002	1,945	2,186	2,229	2,257	2,264	2,217

The Total CRN Recruitment, over Time

	2008/09				2009/10				2010/11				2011/12
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
TOTAL NUMBER OF STUDIES	101,065	87,548	80,007	62,606	100,398	112,233	126,949	114,558	174,820	125,410	124,668	139,800	120,585

Table 3.8 provides summary trend data; it illustrates a quarter on quarter increase in the number of studies open to recruitment which is maintained in quarter 1 2011/12. There is however much more variation in the total number of studies reporting recruitment data in each quarter. A steady increase was observed in each quarter through 2010/11 however this was not maintained in Quarter 1 2011/12

4. NHS RESEARCH MANAGEMENT AND GOVERNANCE ACTIVITY

The NIHR Coordinated System for gaining NHS Permission (CSP) is a system comprising both IT and Clinical Research Network resources, to support researchers in gaining the necessary permissions to carry out a CRN Portfolio study quickly and efficiently, with the minimum of bureaucracy. CSP was introduced in the NHS in England in November 2008.

Responsibility for the various aspects of study set-up (regulatory authorities, NHS research ethics, NHS Permission) sits with a number of bodies. The Clinical Research Network provides a framework for NHS Permission, but is not in a position to control other parallel processes. The CSP system tracks the beginning of the study set-up process through to receipt of NHS Permission to commence the study (which is only given when all other necessary approvals are in place). This data therefore provides a picture of approval times as a whole, as they are experienced by researchers. However it is not a direct indicator of the Clinical Research Network's 'performance' in relation to study approval only.

Figure 4.1 shows the (median) average time to permission for studies per quarter ie the median time for the approvals process for those studies for which NHS permission was issued in that quarter. This reveals the shortest median time to permission through CSP since Quarter 3 2009/10, and a reduction of 32 days compared with the peak figure in Quarter 1 2010/11.

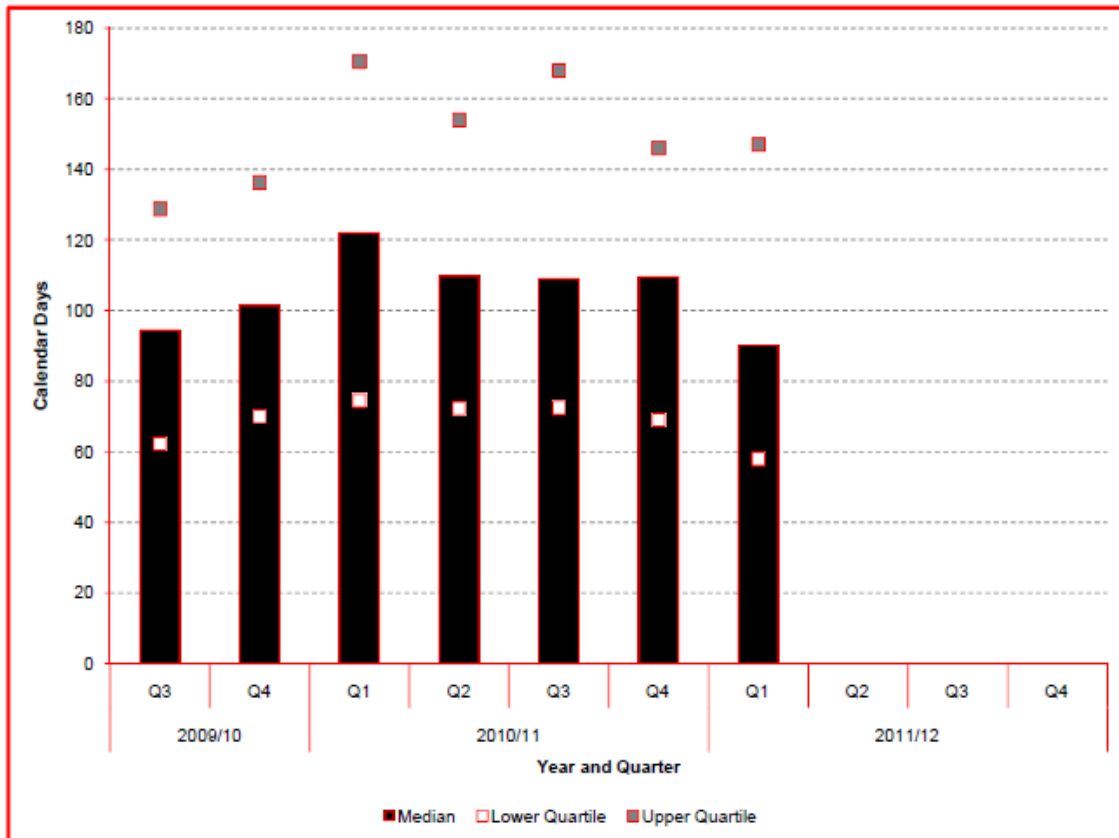
This measure reflects all the sites for which an application has been made in a study. As sites may be set up at various times, the metrics need to reflect this variation in order to avoid double-counting or counting redundant time. In calculating the time to achieve NHS Permission, the following measures are used:

1. Where local permission takes place within the time taken for study-wide checks to be completed, the period measured is R&D form validation to study-wide checks completed
2. Where the SSI form is validated before study-wide checks are completed, but NHS permission is granted after study-wide checks are complete, the period measured is R&D form Validation to Date NHS Permission is granted
3. Where the SSI form is validated after the study-wide checks, the period measured is R&D form validation to study-wide checks completed plus SSI form validation to NHS permission

An improvement programme to address the high median times was instituted in Quarter 3 2010/11. In addition to process changes, from April 2011 a number of changes were made to the definitions and criteria used in the metrics to ensure they reflected the requirements of the High Level Objective. The starting point was changed from the receipt of a valid application form to a valid application package, including appropriate accompanying documents. Initial indications show that removing the time between submission of a form and submission of the accompanying documents is resulting in an improvement to the metrics. This will continue to be monitored but may confirm anecdotal information that researchers have historically been taking weeks or even months to supply the documents necessary for review, even though the documents are the same as those required to be submitted in a single package for ethical review.

From April 2011, in order to more accurately reflect the part of the process that is under the control of the CRN, we have implemented new conditions for the situations in which the clock is 'stopped'. This change may also have had an impact on the median time for permission.

Fig 4.1: Median Average Time to Achieve NHS Permission



Figures 4.2 and 4.3 show a breakdown of the two components of CSP, the study-wide review and the local review.

Figure 4.2 shows the time to complete the study-wide review. This is the time from R&D validation to study-wide review completed. The graph shows data by the quarter in which the study-wide checks were completed. A small downward trend noted in Quarter 4 2010/11 has stabilised for Quarter 1 2011/12. Arrangements are being put in place across the CRN to address lengthy timelines for study set-up, and may be beginning to have an impact. To date, these arrangements have included a greater focus on performance management of studies through CSP by the CLRNs and supporting a more proportionate process to the review of studies. Further activities to improve the performance of CSP are in development and are intended to make an even greater impact on timelines.

Fig 4.2: Median Average Time to Complete Study-Wide Review

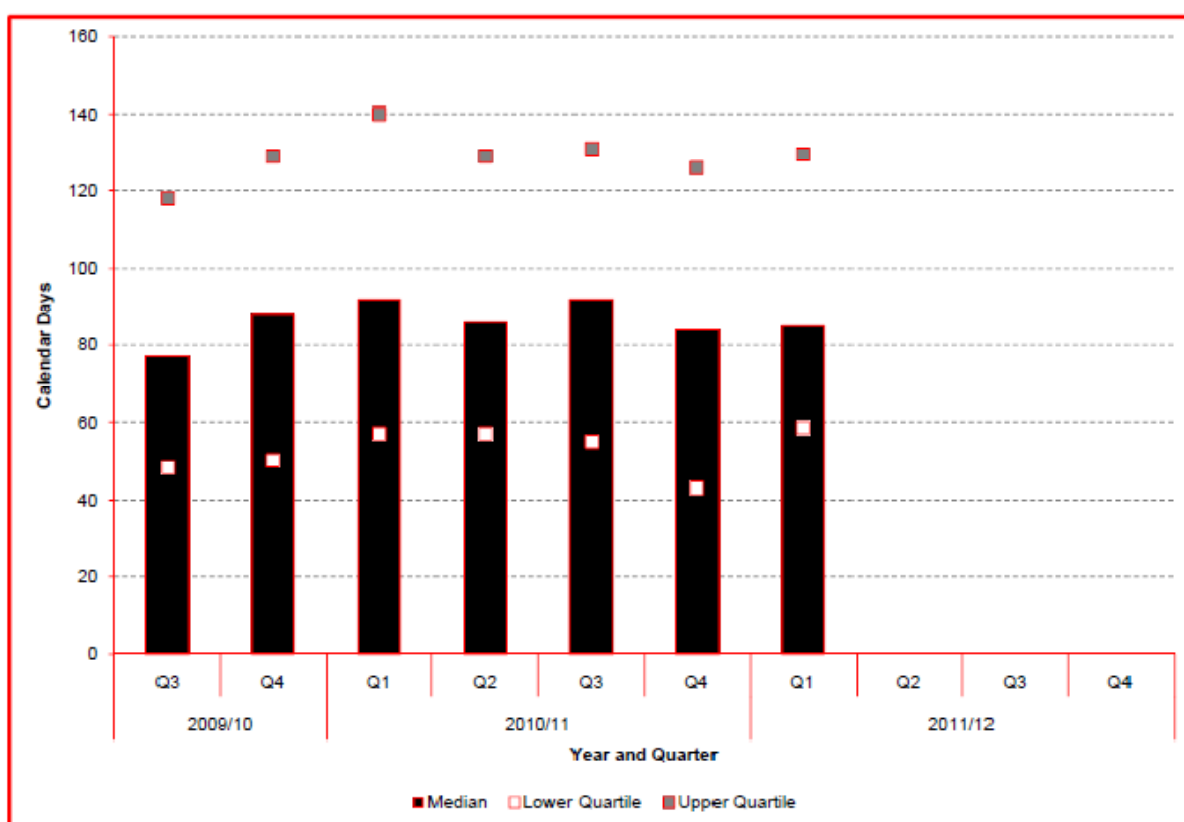


Figure 4.3 shows the time to complete the local review, by the quarter in which the local reviews were completed. This is the time from SSI form to NHS permission. It should be noted that studies may be counted more than once as each study will have local reviews for each site.

These figures are showing an overall downward trend, which suggests that the arrangements being put in place across the CRN to address lengthy timelines for study set-up are beginning to have an impact. The rate of improvement in the speed of local review appears to be greater than the rate of improvement in the study-wide review. It may be that this reflects the greater local control and ownership of local review that is being encouraged through the CLRN.

Fig 4.3: Median Average Time to Complete Local Review

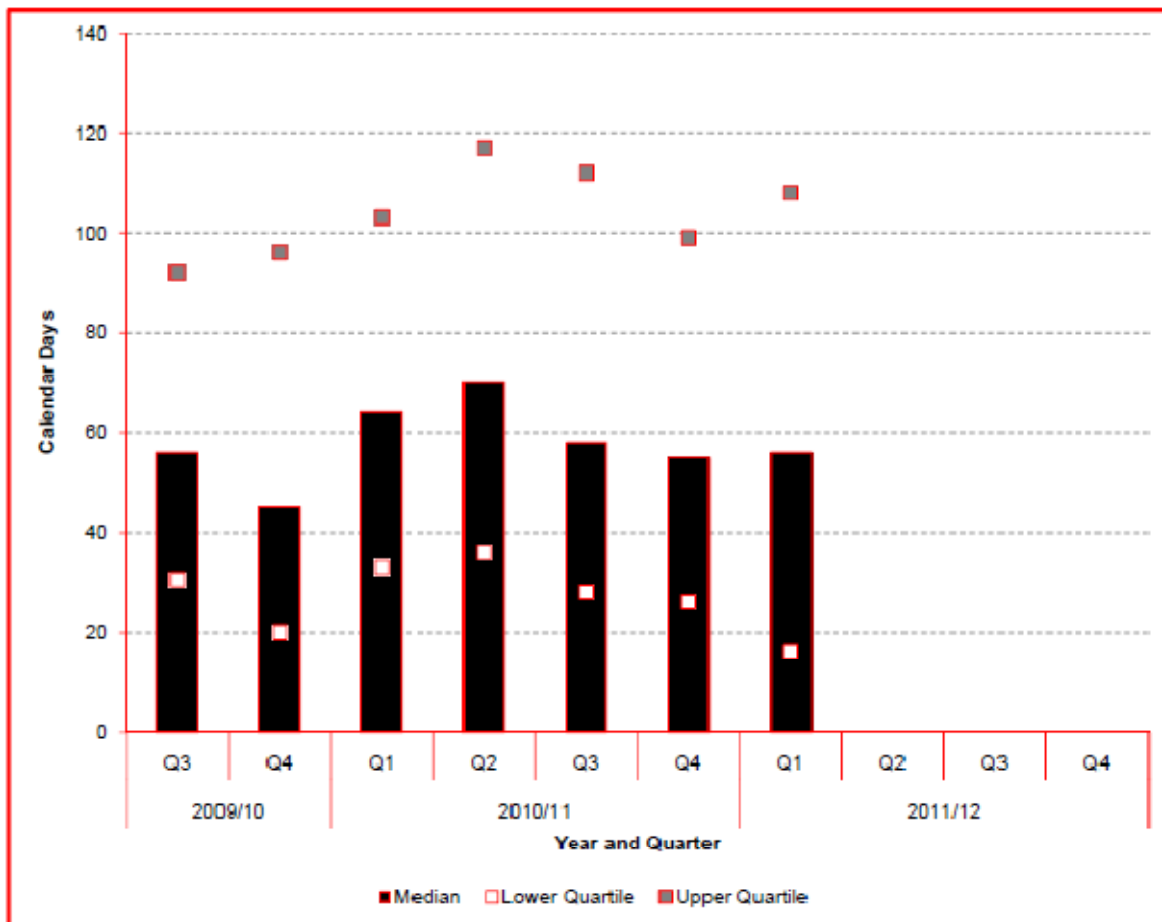
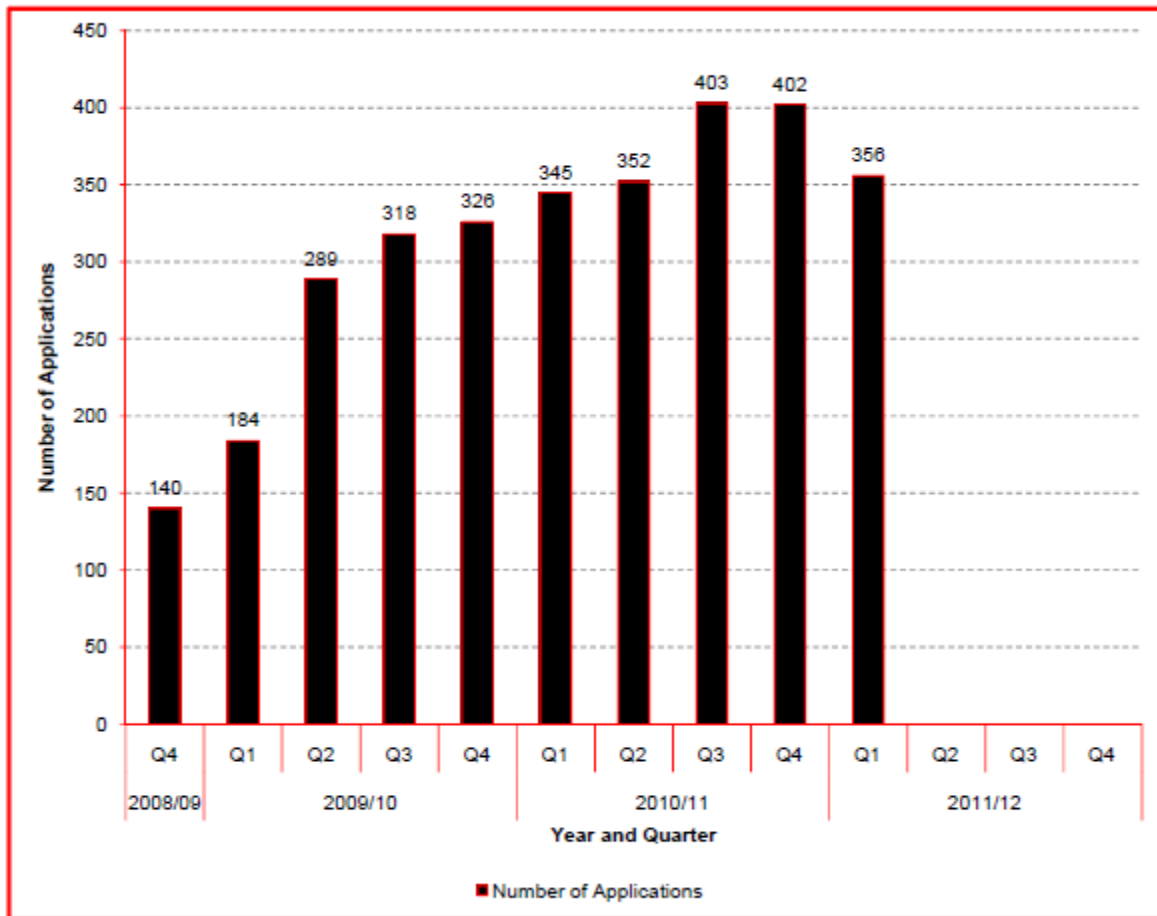


Figure 4.4 shows the number of studies accepted for processing through CSP per month. Some fluctuation month by month is expected, particularly in response to funding rounds and seasonal variations in academic activity. Quarters 3 and 4 2010/11 showed an increase in applications compared with Quarter 1 2011/12, reflecting the seasonal round of funding grants. The pattern does not mirror that in figure 3.1, as there is a lag between the study being registered on CSP and being deemed eligible for consideration for the NIHR Clinical research Network support and then added to the Portfolio Database. The Portfolio eligibility process takes a variable length of time and will not therefore reflect the rate of entry into CSP.

Fig 4.4: Number of Applications via CSP



5. LIFE-SCIENCES INDUSTRY STUDIES

The life-sciences industry continues to be of significant strategic and economic importance to the UK, which is why the Clinical Research Network actively encourages and supports life-sciences companies to undertake clinical research in the NHS in England.

Each quarter, we measure how many NIHR Clinical Research Network Portfolio studies are funded and sponsored by commercial life-sciences companies, as an indicator of the extent to which commercial companies are engaging with the Clinical Research Network and the extent of opportunities for patients to participate in these studies.

Some studies are jointly supported which means that more than one Network is engaged in supporting the research. Where this is the case, a “Lead” Network is appointed. Table 5.1 shows these data. Benefits of joint support include cross-Network referral and participant identification, for example a patient may be identified in Primary Care, but go on to receive treatment through the trial in a secondary care unit. The ability to work “cross-Network” is a benefit of the Clinical Research Network to Industry as it facilitates recruitment of participants across often complex patient treatment pathways.

Med-tech is a specific area of focus and growing area for the Clinical Research Network and specific data on the number of studies in this area is detailed in Table 5.1.

Table 5.1 also tabulates the number of commercial studies that apply for Network support however are NOT adopted onto the NIHR Clinical Research Network Portfolio. When compared with the number of studies that have been adopted, this gives an indication of the relatively small number of studies that progress through the adoption process but is not able to be supported for a variety of reasons. The proportion of studies not being adopted has increased slightly as compared to the last quarter and is 10 %.

Table 5.1: Number of Industry Studies by Network as at 31 March 2011

Clinical Research Network	Total Number of Adopted Industry Studies by Lead Network	Total Number of Adopted Industry Studies by Co-adopting Network	Number of Adopted Industry Studies by Network, Including Co-adopted Studies	Number of Medical Device Studies Included in Total	No. of Studies Which Have NOT Been Adopted
Cancer	192	1	193	1	24
Comprehensive	296	82	378	35	35
DeNDRoN	61	0	61	1	7
Diabetes	113	10	123	9	11
Medicines for Children	127	10	137	2	5
Mental Health	22	2	24	0	3
Primary Care	22	51	73	0	2
Stroke	13	2	15	2	2
TOTAL	846*	158	1004	50	89

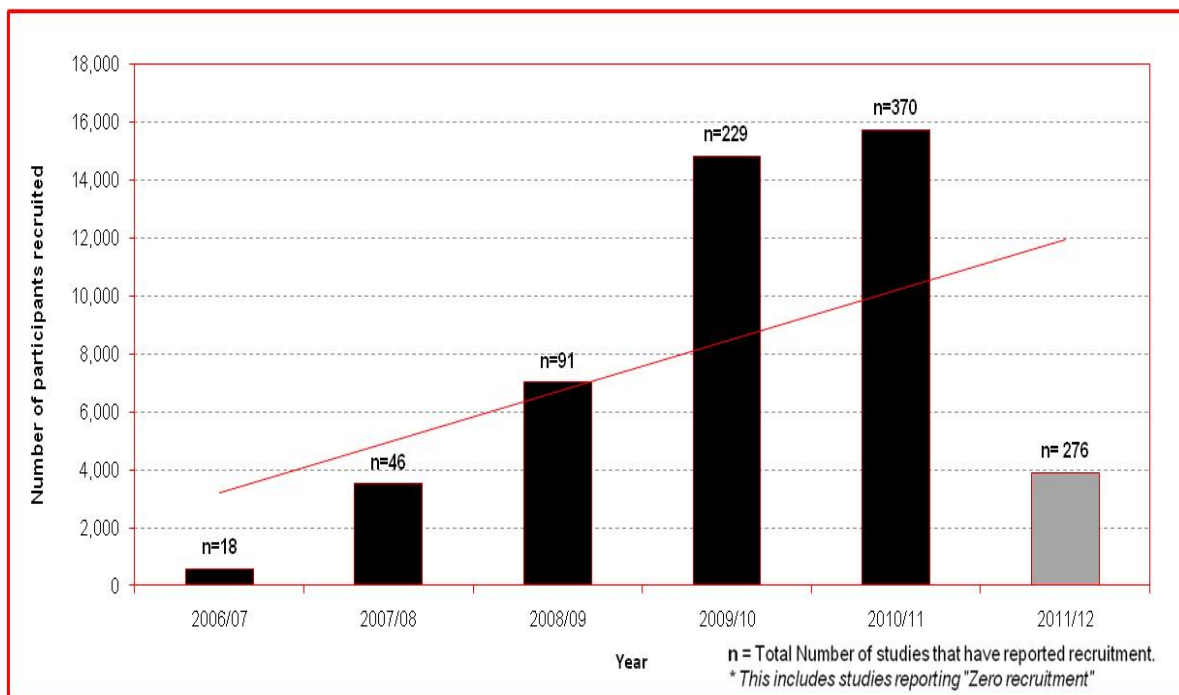
* Total Number of Unique Studies

Trend information:

The NIHR Clinical Research Network continues to expand its portfolio of Industry studies. Table 5.1 highlights the current number of adopted Industry studies, with 87 new studies adopted to date as compared to the last quarter.

- The total number of unique life-sciences studies on the Portfolio to date is 846, compared with 759 reported at the end of Quarter 4 2010/11. This represents continued growth for the Clinical Research Network's commercial Portfolio.
- The number of jointly supported studies on the NIHR CRN Portfolio has increased by 17% (from 135 studies to 158 studies) compared with the last quarter. It demonstrates the increasing partnership and sharing of expertise by the different topic networks when adopting and delivering studies.
- The number of Med-tech studies adopted increased by 11% (from 45 to 50 studies) compared with the last quarter. This increase is marginally less than the last quarter comparison but still demonstrates growth and the continued efforts made by the NIHR Clinical Research Network Industry team to engage with Med-tech companies and highlight the benefits of working with the Networks.

Fig 5.2: Recruitment into Industry Studies for each Operating Year

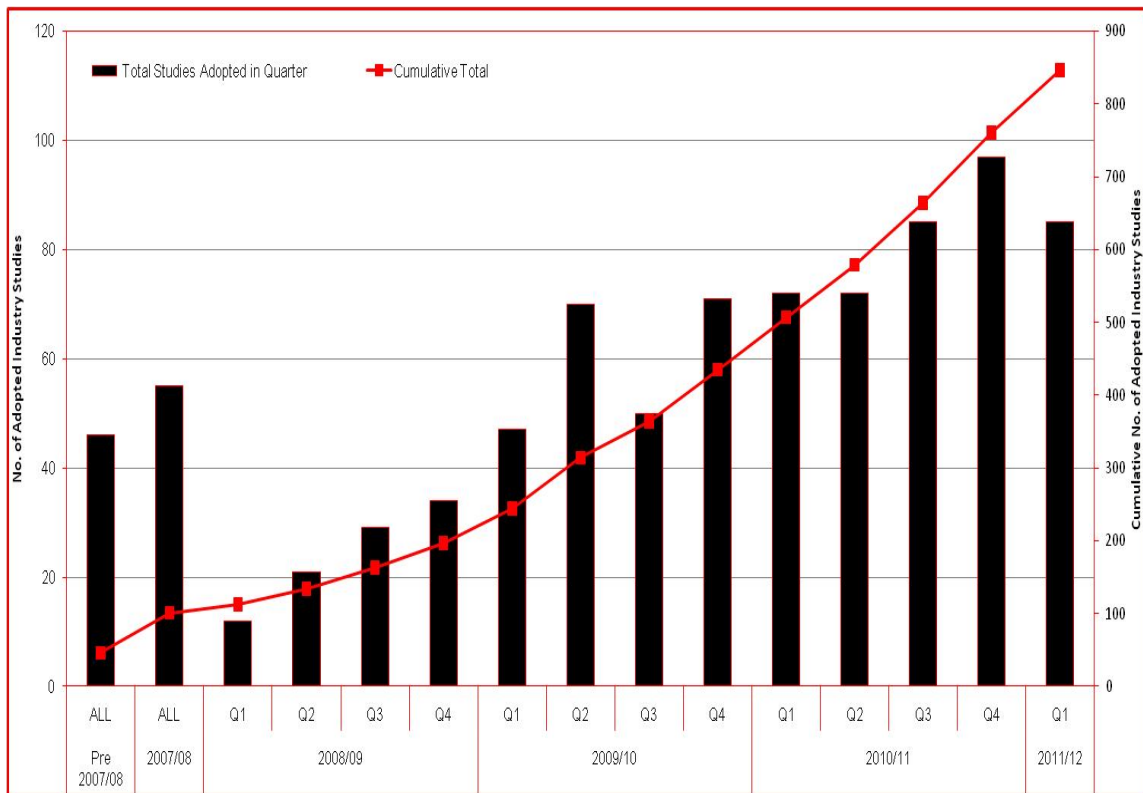


Trend information:

Figure 5.2 shows the level of participant recruitment into NIHR CRN Portfolio studies funded and sponsored by the life-sciences industry. This represents an increased number of participants recruited into studies running in the UK, which are actively supported and performance managed by the Networks.

- 2011/12 recruitment currently stands at 3902 for the year to date, with 276 open studies reporting recruitment in the quarter.
- The number of studies reporting recruitment in Quarter 1 2011/2012 has increased by 39% when compared to Quarter 1 of 2010/2011. This demonstrates continued and positive growth of the Industry portfolio.

Fig 5.3: Number of Adopted Industry Studies over Time



Trend information:

Figure 5.3 illustrates the cumulative trend of continued and positive engagement with Industry as the number of commercial studies adopted continues to increase each year.

There was an increase in the number of studies adopted in Quarter 1 2011/2012 (85 studies) when compared to the number of studies adopted in the same Quarter of the last financial year (72 studies) 2010/2011. This represents an 18% increase and indicates an early positive trend of continued industry engagement with the Clinical Research Network.



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